

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet

1

of

8

APPLICATION NO.: 09/316,199

ATTY. DOCKET NO.: C1040.70006US00

FILING DATE: May 21, 1999

CONFIRMATION NO.: 7506

APPLICANT: McCluskie et al.

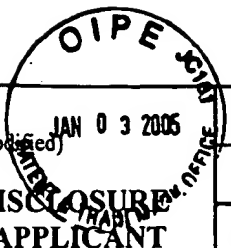
GROUP ART UNIT: ~~1632~~ 1633

EXAMINER:

Dave Trong Nguyen

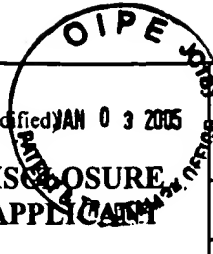
## U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
QW		4,452,775		Kent	06-05-1984
		4,544,559		Gil et al.	10-01-1985
		4,994,442		Gil et al.	02-19-1991
		5,066,500		Gil et al.	11-19-1991
		5,679,647		Carson, et al.	10-21-1997
		5,804,566		Carson et al.	09-08-1998
		5,830,877		Carson et al.	11-03-1998
		5,985,847		Carson et al.	11-16-1999
		6,030,955		Stein et al.	02-29-2000
		6,086,898		DeKruyff et al.	07-11-2000
		6,214,804	B1	Felgner et al.	04-10-2001
		6,248,720	B1	Mathiowitz et al.	06-19-2001
		6,534,062	B1	Raz et al.	03-18-2003
		6,544,518	B1	Friede et al.	04-08-2003
		6,552,006	B2	Raz et al.	04-22-2003
		6,562,798	B1	Schwartz	05-13-2003
		6,589,940	B1	Raz et al.	07-08-2003
		6,653,292	B1	Krieg et al.	11-25-2003
		6,737,066	B1	Moss	05-18-2004
		6,821,957	B1	Davis et al.	11-23-2004
		2001-0034330	A1	Kensil	10-25-2001
		2001-0036462	A1	Fong et al.	11-01-2001
		2001-0044416	A1	McCluskie et al.	11-22-2001
		2001-0046967	A1	Van Nest et al.	11-29-2001
		2002-0028784	A1	Van Nest et al.	03-07-2002
		2002-0042387	A1	Raz et al.	04-11-2002
		2002-0064515	A1	Krieg et al.	05-30-2002
		2002-0086839	A1	Raz et al.	07-04-2002
		2002-0091097	A1	Bratzler et al.	07-11-2002
		2002-0098199	A1	Van Nest et al.	07-25-2002
		2002-0107212	A1	Van Nest et al.	08-08-2002
		2002-0142977	A1	Raz et al.	10-03-2002
		2002-0164341	A1	Davis et al.	11-07-2002
		2002-0165178	A1	Schetter et al.	11-07-2002
		2002-0198165	A1	Bratzler et al.	12-26-2002
		2003-0026801	A1	Weiner et al.	02-06-2003
		2003-0050261	A1	Krieg et al.	03-13-2003
		2003-0050268	A1	Krieg et al.	03-13-2003
QW		2003-0055014	A1	Bratzler	03-20-2003



<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	APPLICATION NO.: 09/316,199		ATTY. DOCKET NO.: C1040.70006US00
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Sheet	2	of	8

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
QW		2003-0087848	A1	Bratzler et al.	05-08-2003
		2003-0091599	A1	Davis et al.	05-15-2003
		2003-0100527	A1	Krieg et al.	05-29-2003
		2003-0104044	A1	Semple et al.	06-05-2003
		2003-0104523	A1	Bauer et al.	06-05-2003
		2003-0125279	A1	Junghans et al.	07-03-2003
		2003-0125292	A1	Semple et al.	07-03-2003
		2003-0130217	A1	Raz et al.	07-10-2003
		2003-0133988	A1	Fearon et al.	07-17-2003
		2003-0138413	A1	Vicari et al.	07-24-2003
		2003-0139364	A1	Krieg et al.	07-24-2003
		2003-0143213	A1	Raz et al.	07-31-2003
		2003-0148316	A1	Lipford et al.	08-07-2003
		2003-0148976	A1	Krieg et al.	08-07-2003
		2003-0165478	A1	Sokoll et al.	09-04-2003
		2003-0166001	A1	Lipford	09-04-2003
		2003-0176389	A1	Raz et al.	09-18-2003
		2003-0181406	A1	Schetter et al.	09-25-2003
		2003-0191079	A1	Krieg et al.	10-09-2003
		2003-0203861	A1	Carson et al.	10-30-2003
		2003-0212026	A1	Krieg et al.	11-13-2003
		2003-0212028	A1	Raz et al.	11-13-2003
		2003-0224010	A1	Davis et al.	12-04-2003
		2003-0232074	A1	Lipford et al.	12-18-2003
		2003-0232780	A1	Carson et al.	12-18-2003
		2004-0006010	A1	Carson et al.	01-08-2004
		2004-0006034	A1	Raz et al.	01-08-2004
		2004-0009942	A1	Van Nest et al.	01-15-2004
		2004-0009949	A1	Krieg	01-15-2004
		2004-0030118	A1	Wagner et al.	02-12-2004
		2004-0053880	A1	Krieg	03-18-2004
		2004-0067905	A1	Krieg	04-08-2004
		2004-0087534	A1	Krieg et al.	05-06-2004
		2004-0087538	A1	Krieg et al.	05-06-2004
		2004-0092468	A1	Schwartz et al.	05-13-2004
		2004-0092472	A1	Krieg	05-13-2004
		2004-0106568	A1	Krieg et al.	06-03-2004
		2004-0115219	A1	Ahn et al.	06-17-2004
	QW	2004-0131628	A1	Bratzler et al.	07-08-2004

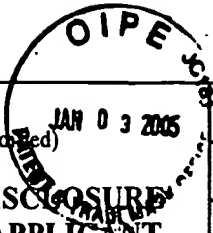


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		Number	Kind Code		
QN		2004-0132685	A1	Krieg et al.	07-08-2004
		2004-0142469	A1	Krieg et al.	07-22-2004
		2004-0143112	A1	Krieg et al.	07-22-2004
		2004-0147468	A1	Krieg et al.	07-29-2004
		2004-0152649	A1	Krieg	08-05-2004
		2004-0152656	A1	Krieg et al.	08-05-2004
		2004-0152657	A1	Krieg et al.	08-05-2004
		2004-0162258	A1	Krieg et al.	08-19-2004
		2004-0162262	A1	Krieg et al.	08-19-2004
		2004-0167089	A1	Krieg et al.	08-26-2004
		2004-0171150	A1	Krieg et al.	09-02-2004
		2004-0171571	A1	Krieg et al.	09-02-2004
		2004-0181045	A1	Krieg et al.	09-16-2004
		2004-0198688	A1	Krieg et al.	10-07-2004

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
QN		EP	1 187 629	A2	Smithkline Beecham Biologicals, S.A.	10-26-2000	
		WO	93/15207	A2	Viagene Inc.	08-05-1993	
		WO	96/13277	A1	Regents of the University of California	05-09-1996	
		WO	96/14074	A1	Regents of the University of California	05-17-1996	
		WO	97/12633	A1	Immunex Corporation	04-10-1997	
		WO	98/01538	A1	Immunex Corporation	01-15-1998	
		WO	98/52962	A1	Merck and Co., Inc.	11-26-1998	
		WO	98/55609	A1	Regents of the University of California	12-10-1998	
		WO	99/33868	A2	Smithkline Beecham Biologicals, S.A.	07-08-1999	
		WO	99/61056	A2	Loeb Health Research Institute at the Ottawa Hospital	12-02-1999	
		WO	00/09159	A1	Aquila Biopharmaceuticals, Inc.	02-24-2000	
		WO	00/15256	A2	Pasteur Merieux Serums Et Vaccins [FR]	03-23-2000	Abstract
		WO	00/23105	A2	Smithkline Beecham Biologicals, S.A.	04-27-2000	
		WO	00/46365	A1	Virginia Commonwealth University	08-10-2000	
		WO	00/54803	A2	Panacea Pharmaceuticals, LLC.	09-21-2000	
		WO	00/56359	A2	Smithkline Beecham Biologicals, S.A.	09-28-2000	
		WO	00/62787	A1	Regents of the University of California	10-26-2000	
		WO	00/62800	A2	SmithKline Beecham Biologicals, S.A.	10-26-2000	
		WO	00/75304	A1	Aventis Pasteur [FR]	12-14-2000	Abstract
		WO	01/00231	A2	SmithKline Beecham Biologicals, S.A.	01-04-2001	
		WO	01/00232	A2	SmithKline Beecham Biologicals, S.A.	01-04-2001	



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Sheet	4	of	8			

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		Office/ Country	Number	Kind Code			
QW		WO	01/17550	A2	SmithKline Beecham Biologicals, S.A.	03-15-2001	
		WO	01/17551	A2	SmithKline Beecham Biologicals, S.A.	03-15-2001	
		WO	01/22972	A2	Coley Pharmaceuticals, GmbH	04-05-2001	
		WO	01/54719	A2	SmithKline Beecham Biologicals, S.A.	08-02-2001	
		WO	01/55341	A2	Regents of the University of California	08-02-2001	
		WO	01/62207	A2	Regents of the University of California	08-30-2001	
		WO	01/62909	A1	Aventis Pasteur [FR]	08-30-2001	Abstract
		WO	01/68077	A2	Dynavax Technologies Corporation	09-20-2001	
		WO	01/68078	A2	Dynavax Technologies Corporation	09-20-2001	
		WO	01/68103	A2	Dynavax Technologies Corporation	09-20-2001	
		WO	01/68116	A2	Dynavax Technologies Corporation	09-20-2001	
		WO	01/68117	A2	Dynavax Technologies Corporation	09-20-2001	
		WO	01/68143	A2	Dynavax Technologies Corporation	09-20-2001	
		WO	01/72123	A1	Regents of the University of California	10-04-2001	
		WO	02/09748	A1	Yale University	02-07-2002	
		WO	02/24225	A1	Glaxo Group Limited [GR]	03-28-2002	
		WO	02/28428	A2	Aventis Pasteur [FR]	04-11-2002	Abstract
		WO	02/074922	A2	Regents of the University of California	09-26-2002	
		WO	02/102307	A2	Ribapharm	12-27-2002	
		WO	03/014316	A2	Dynavax Technologies Corporation	02-20-2003	
		WO	03/020889	A2	3M Innovative Properties Company	03-13-2003	
		WO	03/026688	A1	Pharmaderm Laboratories, Ltd.	04-03-2003	
		WO	03/030934	A2	Qiagen GMBH [DE]	04-17-2003	
		WO	03/094963	A2	INEX Pharmaceuticals Corp.	11-20-2003	
QW		WO	03/100040	A1	Merck Patent GMBH	12-04-2003	

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
QW		ADEREM et al., Toll-like receptors in the induction of the innate immune response. Nature. 2000 Aug 17;406(6797):782-7.	
		ASKEW et al., CpG DNA induces maturation of dendritic cells with distinct effects on nascent and recycling MHC-II antigen-processing mechanisms. J Immunol. 2000 Dec 15;165(12):6889-95.	
		BAUER et al., DNA activates human immune cells through a CpG sequence-dependent manner. Immunology. 1999 Aug;97(4):699-705.	
		BROIDE et al., DNA-Based immunization for asthma. Int Arch Allergy Immunol. 1999 Feb-Apr;118(2-4):453-6.	
		BRUNNER et al., Enhanced dendritic cell maturation by TNF-alpha or cytidine-phosphate-guanosine DNA drives T cell activation in vitro and therapeutic anti-tumor immune responses in vivo. J Immunol. 2000 Dec 1;165(11):6278-86.	
		CALAROTA et al., Cellular cytotoxic response induced by DNA vaccination in HIV-1-infected patients. Lancet. 1998 May 2;351(9112):1320-5.	
QW		CARSON et al., Oligonucleotide adjuvants for T helper 1 (Th1)-specific vaccination. J Exp Med. 1997 Nov 17;186(10):1621-2.	

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FORM PTO-1449/A and B (Modified)

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

Sheet 5 of 8

APPLICATION NO.: 09/316,199

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EXAMINER: Quan Nguyen  
Dave Trong Nguyen

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QW		CHACE et al., Bacterial DNA-induced NK cell IFN-gamma production is dependent on macrophage secretion of IL-12. Clin Immunol Immunopathol. 1997 Aug;84(2):185-93.	
		CHELVARAJAN et al., CpG oligodeoxynucleotides overcome the unresponsiveness of neonatal B cells to stimulation with the thymus-independent stimuli anti-IgM and TNP-Ficoll. Eur J Immunol. 1999 Sep;29(9):2808-18.	
		CHEN et al., Protective immunity induced by oral immunization with a rotavirus DNA vaccine encapsulated in microparticles. J Virol. 1998 Jul;72(7):5757-61.	
		DALPKE et al., Phosphodiester CpG oligonucleotides as adjuvants: polyguanosine runs enhance cellular uptake and improve immunostimulative activity of phosphodiester CpG oligonucleotides in vitro and in vivo. Immunology. 2002 May;106(1):102-12.	
		DEML et al., Immunostimulatory CpG motifs trigger a T helper-1 immune response to human immunodeficiency virus type-1 (HIV-1) gp 160 envelope proteins. Clin Chem Lab Med. 1999 Mar;37(3):199-204.	
		ELKINS et al., Bacterial DNA containing CpG motifs stimulates lymphocyte-dependent protection of mice against lethal infection with intracellular bacteria. J Immunol. 1999 Feb 15;162(4):2291-8.	
		FREIDAG et al., CpG oligodeoxynucleotides and interleukin-12 improve the efficacy of Mycobacterium bovis BCG vaccination in mice challenged with M. tuberculosis. Infect Immun. 2000 May;68(5):2948-53.	
		GOUTTEFANGEAS et al., Problem solving for tumor immunotherapy. Nat Biotechnol. 2000 May;18(5):491-2.	
		HARTMANN et al., CpG DNA and LPS induce distinct patterns of activation in human monocytes. Gene Ther. 1999 May;6(5):893-903.	
		HARTMANN et al., Mechanism and function of a newly identified CpG DNA motif in human primary B cells. J Immunol. 2000 Jan 15;164(2):944-53.	
		HEDLEY et al., Microspheres containing plasmid-encoded antigens elicit cytotoxic T-cell responses. Nat Med. 1998 Mar;4(3):365-8.	
		HEEG et al., CpG DNA as a Th1 trigger. Int Arch Allergy Immunol. 2000 Feb;121(2):87-97.	
		HOPKIN et al., BioMedNet, Issue 57, 6/25/1999.	
		HORNER et al., Optimized conjugation ratios lead to allergen immunostimulatory oligodeoxynucleotide conjugates with retained immunogenicity and minimal anaphylactogenicity. J Allergy Clin Immunol. 2002 Sep;110(3):413-20.	
		HORNER et al., Mucosal adjuvanticity of immunostimulatory DNA sequences. Springer Semin Immunopathol. 2000;22(1-2):133-46.	
		HUANG et al., Induction and regulation of Th1-inducing cytokines by bacterial DNA, lipopolysaccharide, and heat-inactivated bacteria. Infect Immun. 1999 Dec;67(12):6257-63.	
		IHO et al., Oligodeoxynucleotides containing palindrome sequences with internal 5'-CpG-3' act directly on human NK and activated T cells to induce IFN-gamma production in vitro. J Immunol. 1999 Oct 1;163(7):3642-52.	
		IOANNOU et al., The immunogenicity and protective efficacy of bovine herpesvirus 1 glycoprotein D plus Emulsigen are increased by formulation with CpG oligodeoxynucleotides. J Virol. 2002 Sep;76(18):9002-10.	
		JIANG et al., Enhancing immunogenicity by CpG DNA. Curr Opin Mol Ther. 2003 Apr;5(2):180-5. Abstract.	
		JONES et al., Poly(DL-lactide-co-glycolide)-encapsulated plasmid DNA elicits systemic and mucosal antibody responses to encoded protein after oral administration. Vaccine. 1997 Jun;15(8):814-7.	
		JUFFERMANS et al., CpG oligodeoxynucleotides enhance host defense during murine tuberculosis. Infect Immun. 2002 Jan;70(1):147-52.	
		KLINMAN et al., Therapeutic applications of CpG-containing oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Apr;8(2):181-4.	
		KLINMAN et al., Immunotherapeutic applications of CpG-containing oligodeoxynucleotides. Drug News Perspect. 2000 Jun;13(5):289-96.	
QW		KLINMAN et al., Activation of the innate immune system by CpG oligodeoxynucleotides: immunoprotective activity and safety. Springer Semin Immunopathol. 2000;22(1-2):173-83.	

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Sheet	6	of	8

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QW		KRANZER et al. CpG-oligodeoxynucleotides enhance T-cell receptor-triggered interferon-gamma production and up-regulation of CD69 via induction of antigen-presenting cell-derived interferon type I and interleukin-12. Immunology. 2000 Feb;99(2):170-8.	
		KRIEG et al., Immune effects and therapeutic applications of CpG motifs in bacterial DNA. Immunopharmacology. 2000 Jul 25;48(3):303-5.	
		KRIEG et al., American College of Rheumatology 58th National Scientific Meeting. Minneapolis, Minnesota, October 22, 1994. Abstracts. Arthritis Rheum. 1994 Sep;37(9 Suppl).	
		KRIEG et al., CpG motifs in bacterial DNA and their immune effects. Annu Rev Immunol. 2002;20:709-60. Epub 2001 Oct 04.	
		KRIEG et al., Causing a commotion in the blood: immunotherapy progresses from bacteria to bacterial DNA. Immunol Today. 2000 Oct;21(10):521-6.	
		KRIEG et al., Chapter 8: Immune Stimulation by Oligonucleotides. in Antisense Research and Application. Crooke, editor. 1998; 243-62.	
		KRIEG et al., Chapter 17: Immune stimulation by oligonucleotides. in Antisense Drug Tech. 2001;1394:471-515.	
		KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.	
		KRIEG et al., The CpG motif: Implications for clinical immunology. BioDrugs. 1998 Nov 1;10(5):341-6.	
		KRIEG, The role of CpG motifs in innate immunity. Curr Opin Immunol. 2000 Feb;12(1):35-43.	
		KRIEG et al., Mechanism of action of CpG DNA. Curr Top Microbiol Immunol. 2000;247:1-21.	
		KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.	
		KRIEG et al., CpG DNA induces sustained IL-12 expression in vivo and resistance to Listeria monocytogenes challenge. J Immunol. 1998 Sep 1;161(5):2428-34.	
		KRIEG, Signal transduction induced by immunostimulatory CpG DNA. Springer Semin Immunopathol. 2000;22(1-2):97-105.	
		KRIEG, Lymphocyte activation by CpG dinucleotide motifs in prokaryotic DNA. Trends Microbiol. 1996 Feb;4(2):73-6.	
		KRINGEL et al., CpG-oligodeoxynucleotides enhance porcine immunity to Toxoplasma gondii. Vet Parasitol. 2004 Aug 13;123(1-2):55-66.	
		KURAMOTO et al., Induction of T-cell-mediated immunity against MethA fibrosarcoma by intratumoral injections of a bacillus Calmette-Guerin nucleic acid fraction. Cancer Immunol Immunother. 1992;34(5):283-8.	
		LeCLERC et al., The preferential induction of a Th1 immune response by DNA-based immunization is mediated by the immunostimulatory effect of plasmid DNA. Cell Immunol. 1997 Aug 1;179(2):97-106.	
		MacGREGOR et al., First human trial of a DNA-based vaccine for treatment of human immunodeficiency virus type 1 infection: safety and host response. J Infect Dis. 1998 Jul;178(1):92-100.	
		MARTIN-OROZCO et al., Enhancement of antigen-presenting cell surface molecules involved in cognate interactions by immunostimulatory DNA sequences. Int Immunol. 1999 Jul;11(7):1111-8.	
		McCLUSKIE et al., Novel strategies using DNA for the induction of mucosal immunity. Crit Rev Immunol. 1999;19(4):303-29.	
		McCLUSKIE et al., Immunization against hepatitis B virus by mucosal administration of antigen-antibody complexes. Viral Immunol. 1998;11(4):245-52.	
		McCLUSKIE et al., Route and method of delivery of DNA vaccine influence immune responses in mice and non-human primates. Mol Med. 1999 May;5(5):287-300.	
		MERAD et al., Proc Annu Meet Am Assoc Cancer Res. 2001 Mar; 42. Abstract.	
		MITCHELL et al., RNA transfected dendritic cells as cancer vaccines. Curr Opin Mol Ther. 2000 Apr;2(2):176-81.	
		MOSS et al., In vitro immune function after vaccination with an inactivated, gp120-depleted HIV-1 antigen with immunostimulatory oligodeoxynucleotides. Vaccine. 2000 Jan 6;18(11-12):1081-7.	
QW		PENG et al., CpG oligodeoxynucleotide vaccination suppresses IgE induction but may fail to down-regulate ongoing IgE responses in mice. Int Immunol. 2001 Jan;13(1):3-11.	

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JAN 03 2005

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GROUP ART UNIT: 1632 1633 EXAMINER: Dave Phong Nguyen

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QW		PINK et al., 4th meeting on Novel Adjuvants Currently in/close to Human Clinical Testing World Health Organization -- organisation Mondiale de la Sante Fondation Merieux, Annecy, France, 23-25, June 2003. Vaccine. 2004 Jun 2;22(17-18):2097-102.	
		PISETSKY et al., Immunological properties of bacterial DNA. Ann N Y Acad Sci. 1995 Nov 27;772:152-63.	
		PISETSKY, The influence of base sequence on the immunostimulatory properties of DNA. Immunol Res. 1999;19(1):35-46.	
		PISETSKY et al., Immune activation by bacterial DNA: a new genetic code. Immunity. 1996 Oct;5(4):303-10.	
		RANKIN et al., CpG motif identification for veterinary and laboratory species demonstrates that sequence recognition is highly conserved. Antisense Nucleic Acid Drug Dev. 2001 Oct;11(5):333-40.	
		RANKIN et al., CpG-containing oligodeoxynucleotides augment and switch the immune responses of cattle to bovine herpesvirus-1 glycoprotein D. Vaccine. 2002 Jul 26;20(23-24):3014-22.	
		RAY et al., Experimental Biology 2001. Orlando, Florida, USA. March 31-April 4, 2001. Abstracts, part II. FASEB J. 2001 Mar 8;15(5):A1007.	
		ROTHENFUSSER et al., Recent advances in immunostimulatory CpG oligonucleotides. Curr Opin Mol Ther. 2003 Apr;5(2):98-106.	
		SANDLER et al., CpG oligonucleotides enhance the tumor antigen-specific immune response of a granulocyte macrophage colony-stimulating factor-based vaccine strategy in neuroblastoma. Cancer Res. 2003 Jan 15;63(2):394-9.	
		SCHWARTZ et al., Bacterial DNA or oligonucleotides containing unmethylated CpG motifs can minimize lipopolysaccharide-induced inflammation in the lower respiratory tract through an IL-12-dependent pathway. J Immunol. 1999 Jul 1;163(1):224-31.	
		SESTER et al., Phosphorothioate backbone modification modulates macrophage activation by CpG DNA. J Immunol. 2000 Oct 15;165(8):4165-73.	
		SINGH et al., Advances in vaccine adjuvants. Nat Biotechnol. 1999 Nov;17(11):1075-81.	
		SPARWASSER et al., Bacterial DNA causes septic shock. Nature. 1997 Mar 27;386(6623):336-7.	
		STACEY et al. Immunostimulatory DNA as an adjuvant in vaccination against Leishmania major. Infect Immun. 1999 Aug;67(8):3719-26.	
		SUN et al. Type I interferon-mediated stimulation of T cells by CpG DNA. J Exp Med. 1998 Dec 21;188(12):2335-42.	
		SUN et al. Multiple effects of immunostimulatory DNA on T cells and the role of type I interferons. Springer Semin Immunopathol. 2000;22(1-2):77-84.	
		TACKET et al., Phase I safety and immune response studies of a DNA vaccine encoding hepatitis B surface antigen delivered by a gene delivery device. Vaccine. 1999 Jul 16;17(22):2826-9.	
		TIGHE et al., Conjugation of protein to immunostimulatory DNA results in a rapid, long-lasting and potent induction of cell-mediated and humoral immunity. Eur J Immunol. 2000 Jul;30(7):1939-47.	
		TORTORA et al., Oral antisense that targets protein kinase A cooperates with taxol and inhibits tumor growth, angiogenesis, and growth factor production. Clin Cancer Res. 2000 Jun;6(6):2506-12.	
		UGEN et al., DNA vaccination with HIV-1 expressing constructs elicits immune responses in humans. Vaccine. 1998 Nov;16(19):1818-21.	
		UHLMANN et al., Recent advances in the development of immunostimulatory oligonucleotides. Curr Opin Drug Discov Devel. 2003 Mar;6(2):204-17.	
		VOLLMER et al., Highly immunostimulatory CpG-free oligodeoxynucleotides for activation of human leukocytes. Antisense Nucleic Acid Drug Dev. 2002 Jun;12(3):165-75.	
		VOLLMER et al., Characterization of three CpG oligodeoxynucleotide classes with distinct immunostimulatory activities. Eur J Immunol. 2004 Jan;34(1):251-62.	
		WAGNER, Interactions between bacterial CpG-DNA and TLR9 bridge innate and adaptive immunity. Curr Opin Microbiol. 2002 Feb;5(1):62-9.	
		WANG et al., Synergy between CpG- or non-CpG DNA and specific antigen for B cell activation. Int Immunol. 2003 Feb;15(2):223-31.	
QW		WANG et al., Induction of antigen-specific cytotoxic T lymphocytes in humans by a malaria DNA vaccine. Science. 1998 Oct 16;282(5388):476-80.	

O I P E (318)

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FORM PTO-1449/A and B (Modified)

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

APPLICATION NO.: 09/316,199	ATTY. DOCKET NO.: C1040.70006US00
FILING DATE: May 21, 1999	CONFIRMATION NO.: 7506
APPLICANT: McCluskie et al.	
GROUP ART UNIT: 1632 1633	EXAMINER: Dave Taang Nguyen

Sheet 8 of 8

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
QW		WEIGEL et al., Comparative analysis of murine marrow-derived dendritic cells generated by Flt3L or GM-CSF/IL-4 and matured with immune stimulatory agents on the in vivo induction of antileukemia responses. Blood. 2002 Dec 1;100(12):4169-76. Epub 2002 Aug 08.	
		WERNETTE et al., CpG oligodeoxynucleotides stimulate canine and feline immune cell proliferation. Vet Immunol Immunopathol. 2002 Jan 15;84(3-4):223-36.	
		WYATT et al. Combinatorially selected guanosine-quartet structure is a potent inhibitor of human immunodeficiency virus envelope-mediated cell fusion. Proc Natl Acad Sci U S A. 1994 Feb 15;91(4):1356-60.	
		YI et al. Rapid induction of mitogen-activated protein kinases by immune stimulatory CpG DNA. J Immunol. 1998 Nov 1;161(9):4493-7.	
		YI et al. CpG oligodeoxyribonucleotides rescue mature spleen B cells from spontaneous apoptosis and promote cell cycle entry. J Immunol. 1998 Jun 15;160(12):5898-906.	
QW		ZHAO et al., Pattern and kinetics of cytokine production following administration of phosphorothioate oligonucleotides in mice. Antisense Nucleic Acid Drug Dev. 1997 Oct;7(5):495-502.	

EXAMINER:	DATE CONSIDERED:
	7/21/05

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an IDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]



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FORM PTO-1449/A and B (Mgdi) 07/2005

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Sheet 1 of 1

#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
<i>QW</i>		US 2004/0013688	A1	Wise et al.	01-22-2004

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

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